510(k) Summary

Date Prepared: October 21, 2010

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Proprietary Name:

- Sprinter Legend 1.25mm Rapid Exchange Balloon Dilatation Catheter
- Sprinter Legend 1.25mm Over-the-Wire Balloon Dilatation Catheter

Common Name:	Sprinter Legend 1.25mm RX and Sprinter Legend 1.25mm OTW
Device Classification Name:	Cardiovascular Devices Class II, 21 CFR Part 814
Product Code:	74 LOX
Device Description:	The Medtronic Sprinter Legend 1.25mm RX and OTW are balloon dilatation catheters designed to perform Percutaneous Transluminal Coronary Angioplasty (PTCA). Sprinter Legend 1.25mm RX The device consists of a semicompliant balloon mounted on a Rapid Exchange delivery catheter. The Sprinter Legend 1.25mm RX device has an effective length of 142cm. It will be available in a single balloon diameter of 1.25mm and in balloon lengths from 6mm to 20mm. Sprinter Legend 1.25mm OTW The device consists of a semicompliant balloon mounted on an Over-the-Wire delivery catheter. The Sprinter Legend 1.25mm OTW device has an effective length of 152cm. Similar to Sprinter Legend 1.25mm RX, Sprinter Legend 1.25mm OTW will also be available in a 1.25mm balloon diameter and with balloon lengths from 6mm to 20mm.
Indications For Use:	The Sprinter Legend RX and OTW 1.25mm Balloon Dilatation Catheters are indicated as pre-dilatation catheters for enlarging coronary luminal diameters during PCI procedures.
Substantially Equivalent Devices:	The Sprinter Legend 1.25mm RX and OTW Balloon Dilatation Catheters use similar technology, materials and method of operation to the approved predicates Sprinter Legend RX device (1.5-4.0mm) (P790017/S096) and Sprinter OTW Balloon Dilatation Catheter (P790017/S081). The indications for use for these devices are similar to those of Sprinter Legend RX (1.5-4.0mm) and the Sprinter OTW devices. The properties of the Sprinter Legend 1.25mm RX and Sprinter Legend 1.25mm OTW devices to treat disease are identical to previously approved PTCA balloon dilatation catheters outlined above.

Summary of Technological Characteristics:

The Medtronic Sprinter Legend 1.25mm RX and OTW devices consist of a balloon at the distal end of the catheter, which can be inflated and deflated by a coaxial lumen, to a defined diameter at a specific pressure. This means that the inner shaft resides inside the distal outer shaft, leaving an annular space between the two for pressurized fluid to flow. For the OTW product the proximal end of the catheter has a luer for attachment to an inflation device. This bifurcated luer has two legs, one to control inflation and deflation of the catheter and one to allow insertion of a guidewire. The proximal section of the RX catheter is a single lumen stainless hypotube with a single luer port for attachment to an inflation device to control inflation and deflation of the catheter. Both catheters provide a lumen which enables the use of a guidewire to position the catheter. A radiopaque balloon marker, which facilitates imaging under fluoroscopy, enables accurate placement. Shaft markers for brachial and femoral techniques are in place.

Summary of Studies:

The following device integrity testing was completed using Sprinter Legend 1.25mm RX and or OTW devices:

- Catheter Dimensional Measurements & Profile
- Catheter Tensile Strength
- Radiopacity
- Coating Testing
- Balloon Compliance
- System Pressure Capability
- System Fatigue
- Balloon Inflation and Deflation, Performance and Balloon Preparation
- Interaction with Accessories
- Wire Lumen Crush
- Kissing Balloon Technique
- Flexibility & Kink Test
- Dye Flow through a Guide Catheter
- Packaging Integrity Testing

The Medtronic Sprinter Legend 1.25mm RX and OTW Balloon Dilatation Catheters met all specified design and performance requirements.

Summary of Clinical Data:

Overview of Clinical Study

Results of The Sprinter® Legend 1.25mm Trial

Clinical data was required for the Sprinter Legend 1.25mm balloon diameter size to ensure that the technological characteristics of the small diameter balloon did not affect safety or effectiveness.

Study Purpose:
To examine acute outcomes when the Sprinter Legend 1.25 mm OTW balloon catheter is used as a pre-dilatation catheter for enlarging coronary luminal diameters during PCI procedures with subsequent use, in most cases, of another PTCA catheter to complete the dilatation.

Design:
This was a prospective, multi-center, single arm open label study that evaluated acute outcomes when the Sprinter Legend 1.25 mm balloon catheter was used as a predilatation catheter for enlarging coronary luminal diameters during percutaneous coronary intervention (PCI) procedures.
Eligibility was based upon the assessment of the lesion's stenosis being ≥70% and included chronic total occlusions (CTOs). The primary endpoint in this study was the Procedural Success consisting of the following:

- Delivery of the balloon catheter to the target lesion and dilatation of the lesion using the study device.
- No evidence of arterial perforation, flow limiting dissection, reduction in TIMI flow from baseline TIMI or clinically significant arrhythmias following pre-dilatation step with the study device.
- TIMI 3 flow post-dilatation at the conclusion of the PCI procedure.

The secondary endpoints were Device success, Lesion success, In-hospital
MACE, Target Lesion Failure (TLF), Thrombosis, Dissection or perforation,
Balloon Rupture and Arrhythmias.

Device success consists of the following:
• Delivery of the balloon catheter to the target lesion and dilatation of the lesion using the study device
• No evidence of arterial perforation, flow limiting dissection, reduction in TIMI flow from baseline TIMI or clinically significant arrhythmias following predilatation step with the study device.

Lesion Success consists of the following:
• Delivery of the balloon catheter to the target lesion and dilatation of the lesion using any PCI method

A total of 51 patients were enrolled in this study at Two (2) study

sites in the United States. Clinical follow-up was conducted post-procedure until discharge.

Demographics:
Baseline demographic parameters for the enrolled population show that the mean age was 67.3 years and 90.2% (46/51) of the subjects were male. Additionally, 96.1% (49/51) subjects had hyperlipidemia and 96.1% (49/51) had hypertension.

Results:
The primary and secondary endpoint results are presented in Table 1 and 2 below. The combined data collected for the primary endpoint indicates that the procedural success was 100.0% (51/51) for this trial. The rate of device success was 100% (51/51) and that of lesion success was also 100% (54/54).

Table 1: Effectiveness Measures

Primary Endpoint	Sprinter Legend 1.25mm (N=51 Subjects) (N=54 Lesions)
Procedure Success	100.0% (51/51)
Device Success	100.0% (51/51)
Lesion Success *	100.0% (54/54)

* Percentage is based on number of lesions with available data. Percentage is based on available angiographic core lab data and if missing, site reported data of post Sprinter Legend TIMI and Perforation are applied.

Table 2: Principal Safety and Effectiveness Results

Secondary Endpoint	Sprinter Legend (N=51 Subjects) (N=54 Lesions)
Major Adverse Cardiac Event (MACE)	2.0% (1/51)
Death	0.0% (0/51)
Cardiac Death	0.0% (0/51)
Target Vessel MI (TVMI, Medtronic Historic Definition)	2.0% (1/51)
TVMI (ARC Definition)	15.7% (8/51)
Emergent CABG	0.0% (0/51)
Clinically Driven Target Lesion Revascularization (TLR)	0.0% (0/51)
Dissection	0.0% (0/51)
Flow Limiting Dissection	0.0% (0/51)
Clinically Driven Target Vessel Revascularization (TVR)	0.0% (0/51)
Perforation	0.0% (0/51)
Clinical/Angiographic	0.0% (0/51)
Thrombus	0.0% (0/51)

Arrhythmias	0.0% (0/51)
Target Lesion Failure (TLF)	2.0% (1/51)
Target Vessel Failure (TVF)	2.0% (1/51)
Stent Thrombosis (ARC Definite/Probable)1	0.0% (0/44)
Definite	0.0% (0/44)
Probable	0.0% (0/44)

Effectiveness Measures

Procedure Success	100.0% (51/51)
Device Success	100.0% (51/51)
Lesion Success2	100.0% (54/54)

Percentage is based on number of subjects with available data, except:
1 For subjects receiving stents
2 Percentage is based on number of lesions with available data

Conclusion:
The Sprinter® Legend 1.25 mm catheter trial met its primary endpoint of procedural success as well as the endpoints of lesion and device success and demonstrated acceptably low rates of adverse events.

Also, as evidenced by the angiographic core lab, 100% (54/54) of lesions had a resulting TIMI 3 coronary blood flow post-procedure further supporting the efficacy profile of this pre-dilatation catheter. The Sprinter Legend 1.25mm balloon successfully assisted subsequent percutaneous coronary interventions to enlarge coronary luminal diameters from a MLD preprocedure of 0.623mm to 2.173mm post-procedure.

In conclusion, the safety and efficacy data presented in this report illustrate the Sprinter Legend 1.25mm balloon may be used to successfully enlarge coronary luminal diameters during PCI procedures as a pre-dilatation balloon catheter.

Biocompatibility Information:

The testing which supports the biocompatibility of the Medtronic Sprinter Legend 1.25mm RX and OTW Balloon Dilatation Catheter product family is consistent with International Standard ISO10993-1:2009 "Biological Evaluation of Medical devices- Part 1: Evaluation and Testing."

When classified according to this standard, the catheter and dilator included in the Medtronic Sprinter Legend 1.25mm RX and OTW Balloon Dilatation Catheter product family are categorized as external communicating devices with limited exposure i.e. whose contact with circulating blood is $\leq$ 24 hours.

The following Biocompatibility tests were performed:

- Cytotoxicity Using ISO Elution Method
- ASTM Hemolysis Study
- Material Mediated Pyrogen
- ISO Maximization Sensitization Study
- ISO Intracutaneous Study
- ISO Systemic Toxicity Study
- C3a and SC5b-9 Complement Activation Assay Study
- Physicochemical Tests
- ASTM Partial Thromboplastin Time Study (PTT)
- In Vivo Thromboresistance Study in the Dog, Jugular Vein

The biocompatibility evaluation completed verifies that the Medtronic Sprinter Legend 1.25mm RX and OTW Balloon Dilatation Catheters are biocompatible.

Sterilization Validation:

The Medtronic Sprinter Legend 1.25mm RX and OTW Balloon Dilatation Catheters will be sterilized using a validated Ethylene Oxide (EtO) sterilization process.

Conclusion:

Through the data and information presented, Medtronic Ireland considers the Medtronic Sprinter Legend 1.25mm RX and OTW Balloon Dilatation Catheters to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medtronic Ireland
c/o Ms. Gerardine Finn
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3576 Unocal Place
Santa Rosa, CA 95403

OCT 2 2 2010

Re: K103095
Trade/Device Name: Sprinter Legend 1.25mm Rapid Exchange Balloon Dilatation Catheter
Sprinter Legend 1.25mm Over-the-Wire Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: PTCA Catheters
Regulatory Class: Class II (two)
Product Code: LOX
Dated: Not Dated
Received: October 8, 2010

Dear Ms. Finn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K103095 OCT 2 2 2010

Device Name: Medtronic Sprinter Legend 1.25mm RX and Sprinter Legend 1.25mm OTW Balloon Dilatation Catheters

Indications for Use: The Sprinter Legend RX and OTW 1.25mm Balloon Dilatation Catheter is indicated as a pre-dilatation catheter for enlarging coronary luminal diameters during PCI procedures.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K103095